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10 UNITED STATES DISTRICT COURT  
11 EASTERN DISTRICT OF WASHINGTON  
12

13 JEREMY OLSEN,

14 Plaintiff,

15 vs.

16 XAVIER BECERRA, in his official  
17 capacity as Secretary of the United States  
18 Department of Health and Human  
19 Services,  
20

21 Defendant.  
22

No. 2:21-cv-00326-SMJ

SECOND AMENDED ANSWER

23 The Defendant, Xavier Becerra, Secretary of Health and Human Services  
24 (“Defendant”), through counsel, respectfully files this Second Amended Answer to  
25 Plaintiff’s Complaint, ECF No. 1. The Secretary notes that, pursuant to 42 U.S.C.  
26 § 1395ff(b)(1)(A), the Court’s review in this action is based solely on the  
27 administrative record, rather than the allegations of the parties in their respective  
28 pleadings.

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SECOND AMENDED ANSWER - 1

**PREFATORY STATEMENT**

“It is often better to acknowledge an obvious mistake than defend it.” *Gate Guard Servs., L.P. v. Perez*, 792 F.3d 554, 555 (5th Cir. 2015). There are two claims for Medicare reimbursement at issue in this case. The first is for a 90-day supply of continuous glucose monitor (“CGM”) sensors with a date of service of April 19 – July 18, 2019 (the “April 2019 claim”). The second is for a 90-day supply of CGM sensors with a date of service of March 10, 2021 (the “March 2021 claim”). Defendant concedes that the Secretary erred in denying coverage for both claims. First and foremost, Plaintiff was entitled to have these claims covered based on *res judicata* after judgment was entered in his favor in *Olsen v. Becerra*, Case No. 20-cv-00374-SMJ (“*Olsen I*”), consistent with the Secretary’s practice of paying such claims for beneficiaries who receive court judgments in their favor.<sup>1</sup> Additionally, the Secretary’s recently-issued Durable Medical Equipment (“DME”) final rule makes clear that claims submitted for CGM sensors and transmitters used with insulin pumps, like the Medtronic MiniMed device that Plaintiff uses, were “being denied inappropriately based on” CMS Ruling 1682-R (Jan. 12, 2017), *see* 86 Fed. Reg. 73,860, 73,898 (Dec. 28, 2021), and that error also occurred here.<sup>2</sup>

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<sup>1</sup> See Decl. of Larry D. Young ¶¶ 3–5, ECF No. 32-1, *Lewis v. Becerra*, No. 18-CV-02929 (July 12, 2019) (explaining that the claims of beneficiaries who have won court judgments are treated differently than ordinary claims).

<sup>2</sup> The December 2021 Final Rule explained that CMS Ruling 1682-R “only addressed the classification of CGM receivers as DME and did not address coverage of CGM sensors and transmitters used with insulin pumps.” 86 Fed. Reg. at 73,898. Further,

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1 Defendant is diligently investigating why the Secretary denied coverage for  
2 these claims after the *Olsen I* judgment was entered.<sup>3</sup> From the information available  
3 to date, it appears that two independent errors were made. First, the Secretary did not  
4 promptly inform its Medicare Administrative Contractor (“MAC”) of the *Olsen I*  
5 judgment after it was entered. Second, it appears that the Secretary neglected to  
6 advise the entities responsible for deciding Plaintiff’s administrative appeals of the  
7 *Olsen I* judgment and to instruct those entities to resolve the appeals in Plaintiff’s  
8 favor.  
9

10  
11 What is known for certain, however, is that the April 2019 and March 2021  
12 claims were paid by the MAC, at the Secretary’s direction and in response to the  
13 *Olsen I* judgment, on **July 15, 2021**. As of that date, Plaintiff had the coverage to  
14 which he was entitled, and his administrative appeals should have been dismissed.  
15  
16

17 Consistent with the admissions herein, Plaintiff is entitled to an administrative  
18 remand to the Secretary with instructions to vacate: (1) the October 22, 2021 decision  
19  
20

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21 the Final Rule explains that the Secretary “now believe[s] that ... glucose sensors and  
22 transmitters used with insulin pumps ... are primarily and customarily used to serve a  
23 medical purpose.” *Id.* at 73,899.

24 <sup>3</sup> Defendant previously stated that these claims were erroneously denied because the  
25 Secretary’s Medicare Administrative Contractor failed to make a manual adjustment  
26 to the submission code assigned to the claims. ECF No. 4 at ¶ 3; ECF No. 16 at ¶ 3.  
27 Defendant has since determined, through further investigation, that that statement was  
28 not accurate. The Secretary *did* erroneously deny one reimbursement claim for CGM  
sensors on that basis (for date of service October 13, 2021), but that claim is not one  
of the two at issue in this lawsuit.

1 by the Medicare Appeals Council purporting to deny coverage for the April 2019  
2 claim; and (2) the October 26, 2021 decision by an ALJ purporting to deny coverage  
3 for the March 2021 claim.<sup>4</sup> Plaintiff is entitled to an award of costs and attorney's  
4 fees under the Equal Access to Justice Act. Judgment should be entered in Plaintiff's  
5 favor to that effect.  
6

## 7 I. INTRODUCTION

8  
9 1. This paragraph consists of Plaintiff's legal conclusions and  
10 characterization of this lawsuit, to which no response is required.

11 2. Defendant admits that Plaintiff previously filed a lawsuit with respect to  
12 coverage of CGM claims in *Olsen I*. Defendant further admits that Plaintiff obtained a  
13 judgment ordering coverage of his CGM claims in *Olsen I*, and that attorney's fees  
14 were awarded to Plaintiff at market rates. The remainder of this paragraph consists of  
15 Plaintiff's legal conclusions and characterization of this lawsuit, to which no response  
16 is required. The Court is respectfully referred to its prior decision for an accurate and  
17 complete statement of its contents.  
18  
19  
20

21 3. Defendant admits that he erroneously rejected Plaintiff's CGM claims  
22

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23 <sup>4</sup> Defendant recently completed notice and comment rulemaking that culminated in  
24 the publication of a final rule that confirms that disposable sensors that work with  
25 plaintiff's insulin pump are covered "durable medical equipment" under Medicare  
26 Part B. *See* 86 Fed. Reg. 73860, 73896-902, (Dec. 28, 2021), available [here](#). Further,  
27 the new rule replaced CMS Ruling 1682-R on a prospective basis, and Medicare now  
28 covers *all* CGMs and their supplies. That new rule, which took effect on February 28,  
2022, effectively ensures that future CGM claims submitted by Plaintiff and other  
similarly-situated Medicare claimants will be covered.

1 after entry of the Court's decision in *Olsen I*. Defendant denies that he acted in bad  
2 faith. Defendant affirmatively avers that both claims were paid in response to the  
3 *Olsen I* judgment on July 15, 2021, as reflected in Paragraphs 64 and 70 below. The  
4 remainder of this paragraph consists of Plaintiff's legal conclusions and  
5 characterization of this lawsuit, to which no response is required.  
6

7         4. Defendant admits that he erroneously denied coverage for Plaintiff's  
8 CGM claims, after judgment was entered in Plaintiff's favor in *Olsen I*. Defendant  
9 affirmatively avers that both claims were paid on July 15, 2021, as reflected in  
10 Paragraphs 64 and 70 below. Defendant denies the remainder of the allegations in this  
11 paragraph.  
12

13  
14         5. Defendant admits that he erroneously denied coverage for Plaintiff's  
15 CGM claims, after judgment was entered in Plaintiff's favor in *Olsen I*. Defendant  
16 affirmatively avers that both claims were paid on July 15, 2021, as reflected in  
17 Paragraphs 64 and 70 below. Defendant denies the remainder of the allegations in this  
18 paragraph.  
19

20  
21         6. This paragraph consists of Plaintiff's characterization of this lawsuit and  
22 his claims for relief, to which no response is required. To the extent a response is  
23 required, Defendant admits that he erroneously denied coverage for Plaintiff's CGM  
24 claims, after judgment was entered in Plaintiff's favor in *Olsen I*. Defendant  
25 affirmatively avers that both claims were paid on July 15, 2021, as reflected in  
26 Paragraphs 64 and 70 below. Defendant denies that the denial of those CGM claims  
27  
28

1 was a result of bad faith as opposed to mistake. Defendant admits Plaintiff is entitled  
2 to have his CGM claims covered, and Defendant has, in fact, paid all of Plaintiff's  
3 submitted claims mentioned in the Complaint; those claims have been paid as  
4 delineated in Paragraph 76 herein. Defendant denies Plaintiff is entitled to any other  
5 requested relief.  
6

## 7 **II. JURISDICTION**

8  
9 7. This paragraph consists of Plaintiff's legal conclusions regarding subject-  
10 matter jurisdiction, to which no response is required.

11 8. This paragraph consists of Plaintiff's legal conclusions regarding subject-  
12 matter jurisdiction, to which no response is required.<sup>5</sup>  
13

14 9. This paragraph consists of Plaintiff's legal conclusions regarding venue,  
15 to which no response is required.  
16

## 17 **III. PARTIES**

18 10. Admitted.

19 11. Admitted.  
20

## 21 **IV. FACTUAL BACKGROUND**

22 12. Defendant admits that Plaintiff previously filed a lawsuit with respect to  
23 claim for CGM coverage in *Olsen I* which contained Plaintiff's information and  
24  
25

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26 <sup>5</sup> Plaintiff failed to exhaust his administrative remedies as to the March 2021 claim.  
27 Defendant is voluntarily waiving this defense in the interest of bringing this case to a  
28 swift and fair conclusion.

1 allegations regarding diabetes and Plaintiff's characterization of the Medicare appeals  
2 process.

3 **A. Durable Medical Equipment**  
4

5 13. Defendant admits that 42 U.S.C. § 1395x(n) defines "durable medical  
6 equipment." The remainder of this paragraph consists of Plaintiff's legal  
7 characterization of Medicare coverage for "durable medical equipment" under 42  
8 U.S.C. § 1395x(n), to which no response is required. The Court is respectfully referred  
9 to the cited statutory provision for an accurate and complete statement of its contents.  
10

11 14. Defendant admits that 42 U.S.C. § 1395x(n) includes "blood glucose  
12 monitor" as an example of "durable medical equipment." The Court is respectfully  
13 referred to the cited statutory provision for an accurate and complete statement of its  
14 contents.  
15

16 15. Defendant admits that the Secretary has issued regulations found at 42  
17 C.F.R. § 414.202 relating to "durable medical equipment." The remainder of this  
18 paragraph consists of Plaintiff's characterization the Secretary's regulations, to which  
19 no response is required. The Court is respectfully referred to the cited regulation for  
20 an accurate and complete statement of its contents.  
21

22 16. Admitted that 42 C.F.R. § 414.202 contains the cited language, except  
23 with respect to paragraph 16(b) of the Complaint, which is missing words from the  
24 corresponding paragraph of 42 C.F.R. § 414.202. The complete second paragraph of  
25 the definition of durable medical equipment in 42 C.F.R. § 414.202 states: "Effective  
26  
27  
28

1 with respect to items classified as DME after January 1, 2012, has an expected life of  
2 at least 3 years.” Defendant denies that this paragraph contains the full definition of  
3 “durable medical equipment” that is contained in 42 C.F.R. § 414.202; the regulation  
4 also specifies that durable medical equipment must be “furnished by a supplier or a  
5 home health agency.” The Court is respectfully referred to the cited regulation for an  
6 accurate and complete statement of its contents.  
7

8  
9 **B. CMS-1682-R**

10 17. This paragraph consists of a block quotation of a statutory provision.  
11 Defendant admits 42 U.S.C. § 1395hh(a)(2) contains the quoted language without the  
12 added emphasis. The Court is respectfully referred to the cited statutory provision for  
13 an accurate and complete statement of its contents.  
14

15 18. Defendant admits that 42 U.S.C. § 1395hh is applicable to the Secretary’s  
16 “[a]uthority to prescribe regulations; ineffectiveness of substantive rules not  
17 promulgated by regulation[.]” The remainder of this paragraph consists of Plaintiff’s  
18 characterizations and legal conclusions regarding the statutory provision, to which no  
19 response is required. The Court is respectfully referred to the cited statutory provision  
20 for an accurate and complete statement of its contents.  
21

22 19. Defendant admits that CMS Ruling 1682-R was issued on January 12,  
23 2017. The phrase “final opinions and orders” appears in the prefatory statement of all  
24 CMS Rulings. Denied that the phrase “final opinion and order” appears in the  
25 substantive body of CMS Ruling 1682-R. Plaintiffs’ characterizations of CMS Ruling  
26

1 1682-R are denied, except to admit that CMS Ruling 1682-R was not subject to notice  
2 and comment. The Court is respectfully referred to the cited CMS Ruling.

3 20. Admitted that CMS Ruling 1682-R was issued on January 12, 2017, and  
4 that the phrase “binding on all CMS components, on all Department of Health and  
5 Human Services components that adjudicate matters under the jurisdiction of CMS,  
6 and on the Social Security Administration” appears in CMS Ruling 1682-R, at page 1.  
7 The Court is respectfully referred to the cited CMS Ruling for an accurate and  
8 complete statement of its contents.  
9

10 21. This paragraph contains Plaintiff’s characterizations of CMS Ruling  
11 1682-R. The Court is respectfully referred to the cited CMS Ruling for an accurate  
12 and complete statement of its contents.  
13

14 22. Admitted that CMS Ruling 1682-R contains the quoted language.  
15 Plaintiff’s characterizations of CMS Ruling 1682-R are denied. The Court is  
16 respectfully referred to the cited CMS Ruling for an accurate and complete statement  
17 of its contents.  
18

19 23. Plaintiff’s characterizations of CMS Ruling 1682-R are denied. The  
20 Court is respectfully referred to the cited CMS Ruling for an accurate and complete  
21 statement of its contents.  
22

23 24. Admitted that the Secretary denied coverage of certain continuous  
24 glucose monitors on the grounds that they were not “primarily and customarily used to  
25 serve a medical purpose” within the meaning of the Medicare regulations. The  
26

1 Secretary otherwise lacks sufficient knowledge or information to form a belief about  
2 the truth of these factual allegations. Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the  
3 Court's review in this action is based solely on the administrative record, rather than  
4 the allegations of the parties in their respective pleadings; Defendant thus respectfully  
5 refers the Court to the administrative record for an accurate and complete statement of  
6 its contents. To the extent that these factual allegations are not reflected in the  
7 administrative record, they are beyond the scope of the Court's review in this case.  
8  
9

10 25. Denied.

11 26. Admitted that Local Coverage Determination L33822 was revised in  
12 January 2017 to account for CMS Ruling 1682-R., and that this revision was not  
13 preceded by a public comment period. The Court is respectfully referred to Local  
14 Coverage Determination L33822 for an accurate and complete statement of its  
15 contents.  
16  
17

18 27. Admitted that Policy Article A52464 was revised on January 12, 2017, to  
19 account for CMS Ruling 1682-R, and that this revision was not preceded by notice  
20 and an opportunity to comment. The Court is respectfully referred to Policy Article  
21 A52464 for an accurate and complete statement of its contents.  
22

23 28. This paragraph consists of Plaintiff's characterization and legal  
24 conclusions regarding CMS Ruling 1682-R, to which no response is required, but to  
25 the extent a response is deemed required, denied. The Court is respectfully referred to  
26 CMS Ruling 1682-R for an accurate and complete statement of its contents.  
27  
28

1           29.   Admitted.

2           30.   Admitted.

3           31.   This paragraph consists of Plaintiff's characterizations and legal  
4 conclusions regarding the treatment of continuous glucose monitors under Medicare  
5 Part B, to which no response is required. To the extent a response is deemed required,  
6 the Secretary lacks sufficient knowledge or information to form a belief about the  
7 truth of this statement.  
8  
9

10 **C.   Other Litigation Related to CGMs**

11           32.   Denied as to the phrase "in general." Admitted that the Secretary denied  
12 coverage of certain continuous glucose monitors on the grounds that they were not  
13 "primarily and customarily used to serve a medical purpose" within the meaning of  
14 the Medicare Part B regulations. Defendant denied coverage for non-therapeutic (*i.e.*,  
15 "adjunctive") CGMs under the authority of CMS Ruling 1682-R; therapeutic (*i.e.*,  
16 "non-adjunctive") CGMs were classified as "durable medical equipment" under CMS  
17 Ruling 1682-R, and have thus been covered. Denied to the extent the paragraph  
18 suggests that the Secretary currently "contends" that CGMs are not primarily and  
19 customarily used to serve a medical purpose.  
20  
21  
22

23           33.   Admitted that the Secretary previously adhered to the view that some  
24 continuous glucose monitors are not covered as durable medical equipment. Denied to  
25 the extent the statement suggests that the Secretary currently "contends" that a CGM  
26 is excluded from coverage as precautionary. The second sentence in this paragraph  
27  
28

1 consists of Plaintiff's characterizations and legal conclusions regarding Local  
2 Coverage Article A52464, which are denied. The Court is respectfully referred to  
3 Local Coverage Article A52464 for an accurate and complete statement of its  
4 contents.  
5

6 34. Admitted that several district courts have reviewed Medicare Part B  
7 coverage determinations for continuous glucose monitors, including this Court in  
8 *Olsen I.*  
9

10 35. Admitted that some administrative law judges have concluded that  
11 certain continuous glucose monitors are covered as durable medical equipment under  
12 the Medicare statute and regulations. The remainder of this paragraph consists of  
13 Plaintiff's characterizations and legal conclusions regarding decisions by Medicare  
14 Administrative Law Judges, to which no response is required. The Court is  
15 respectfully referred to the cited decisions for accurate and complete statements of  
16 their contents.  
17  
18

19 36. Admitted that several district courts have reviewed Medicare Part B  
20 coverage determinations for continuous glucose monitors, including this Court in  
21 *Olsen I.* Admitted that certain district courts have concluded that continuous glucose  
22 monitors are covered as durable medical equipment under the Medicare Part B statute  
23 and regulations.  
24  
25

26 37. Admitted that certain district courts have concluded that continuous  
27 glucose monitors are covered as durable medical equipment under the Medicare Part  
28

1 B statute and regulations and ordered the Secretary to provide coverage. The  
2 remainder of this paragraph consists of Plaintiff's characterizations and legal  
3 conclusions regarding several district court decisions, to which no response is  
4 required. The Court is respectfully referred to the cited decisions for an accurate and  
5 complete statement of their contents.  
6

7 38. Defendant admits the cited decision contains the quoted language. The  
8 remainder of this paragraph consists of Plaintiff's characterizations and legal  
9 conclusions regarding the district court's decision in *Whitcomb v. Azar*, to which no  
10 response is required. The Court is respectfully referred to that decision for an accurate  
11 and complete statement of its contents.  
12

13 39. Defendant admits the four cited decisions contain the quoted language  
14 and the plaintiffs in those actions were awarded attorney's fees. The remainder of this  
15 paragraph consists of Plaintiff's characterizations and legal conclusions regarding  
16 several district court decisions, to which no response is required. The Court is  
17 respectfully referred the cited decisions for an accurate and complete statement of  
18 their contents.  
19

20 40. The Secretary denies the characterization of the cited administrative  
21 decision, which speaks for itself. The Court is respectfully referred to the cited  
22 decision for a full and complete statement of its contents.  
23

24 **D. Facts Specific to Mr. Olsen**  
25

26 41. Admitted.  
27

1 42. Admitted.

2 43. Admitted.

3 44. Admitted.

4 45. Admitted.

5 46. Admitted.

6 47. Admitted.

7 48. Admitted.

8 49. Admitted.

9  
10  
11 **E. Prior Litigation Before This Court**

12  
13 50. Admitted.

14 51. Admitted.

15 52. Admitted.

16 53. Admitted.

17 54. Admitted.

18  
19 55. Defendant admits this Court granted judgment in Plaintiff's favor in  
20  
21 *Olsen I* (ECF No. 39). Defendant admits the cited decision contains the quoted  
22 language and that this Court concluded that Plaintiff's CGM is covered as durable  
23 medical equipment under the Medicare Part B statute and regulations. The Court is  
24 respectfully referred to its prior decision for an accurate and complete statement of its  
25 contents.  
26

27 56. Admitted this Court's decision in *Olsen I* did not address the issuance of  
28

1 CMS 1682-R. Defendant denies Plaintiff's characterizations of the issuance of CMS  
2 1682-R. The Court is respectfully referred to its prior decision for an accurate and  
3 complete statement of its contents.

4  
5 57. Admitted.

6 58. Defendant admits the allegations in Paragraph 58, with the caveat that the  
7 Court's ruling was specific to the facts presented in *Olsen I*.

8  
9 59. Defendant denies the characterizations of the Court's attorney fee ruling  
10 in *Olsen I* (ECF No. 50), which speaks for itself. The Court is respectfully referred to  
11 its prior decision for an accurate and complete statement of its contents.

12  
13 60. Admitted.

14 **V. The Claims at Issue in this Case**

15 61. Defendant admits that he erroneously denied coverage for Plaintiff's  
16 CGM claims during the administrative appeals process, after judgment was entered in  
17 Plaintiff's favor in *Olsen I*. Defendant affirmatively avers that both claims were paid  
18 on July 15, 2021, during the pendency of the administrative appeals process, as  
19 reflected in Paragraphs 64 and 70 below. Defendant denies the remainder of the  
20 allegations in this paragraph.

21  
22 62. Defendant admits that he erroneously denied coverage for Plaintiff's  
23 CGM claims during the administrative appeals process, after judgment was entered in  
24 Plaintiff's favor in *Olsen I*. Defendant affirmatively avers that both claims were paid  
25 on July 15, 2021, during the pendency of the administrative appeals process, as  
26  
27  
28

1 reflected in Paragraphs 64 and 70 below. Defendant denies the remainder of the  
2 allegations in this paragraph.

3 **A. April 19 – July 18, 2019 Claim –**  
4 **ALJ Appeal No. 3-8946502107/M-20-1269**

5 63. Admitted.

6  
7 64. Defendant admits that the April 2019 claim was: denied initially by the  
8 Secretary’s Medicare Administrative Contractor, Noridian Healthcare Solutions  
9 (“Noridian”), on June 14, 2019; denied on redetermination by Noridian on July 25,  
10 2019; denied on reconsideration by the Secretary’s Qualified Independent Contractor,  
11 Maximus Federal, on November 26, 2019; and denied by an administrative law judge  
12 (“ALJ”) on January 31, 2020. Defendant further admits that the basis for each of  
13 these denials was CMS Ruling 1682-R, which stated that Medicare would not cover  
14 CGMs approved by the Food and Drug Administration for “use as adjunctive devices  
15 to complement, not replace, information obtained from blood glucose monitors”  
16 because Medicare did not consider such “adjunctive” or “non-therapeutic” devices to  
17 serve the medical purpose of making diabetes treatment decisions; Plaintiff  
18 characterizes this as “the ‘bad faith’ grounds.” Defendant affirmatively avers that  
19 these denials occurred prior to the judgment and bad faith ruling in *Olsen I*, which  
20 were entered on February 23, 2021, and April 20, 2021, respectively. On that basis, to  
21 the extent Plaintiff has alleged that Defendant denied this claim in defiance of the  
22 *Olsen I* judgment and bad faith ruling, Defendant denies the allegation. Defendant

1 affirmatively avers that this claim was paid by Noridian on July 15, 2021, at the  
 2 Secretary's direction, in response to the *Olsen I* judgment and bad faith ruling. Below  
 3 is a timeline of when this claim was paid in relation to the decisions referenced above:

4	April 19 - July 18, 2019 Claim	Date
5	Initial Denial by Noridian (MAC)	6/14/2019
6	Redetermination Request (MAC)	7/5/2019
7	Redetermination Decision (MAC)	7/25/2019
8	Reconsideration Request (QIC)	10/7/2019
9	Reconsideration Decision (QIC)	11/26/2019
10	ALJ Hearing Request	12/3/2019
11	ALJ Hearing	1/8/2020
12	ALJ Decision	1/31/2020
13	Appeal to Medicare Appeals Council	2/11/2020
14	<i>Olsen I</i> Judgment	2/23/2021
15	<i>Olsen I</i> Bad Faith Ruling	4/20/2021
16	CLAIM PAID	7/15/2021
17	Medicare Appeals Council Decision	10/22/2021

18 65. Admitted.

19 66. Defendant admits that the Medicare Appeals Council issued a decision  
 20 dated October 22, 2021, denying coverage for the April 2019 claim. Defendant  
 21 admits that the basis for this denial was CMS Ruling 1682-R, which Plaintiff  
 22 characterizes as "the 'bad faith' grounds." Defendant denies that the Medicare  
 23 Appeals Council's October 22, 2021, decision had the legal effect of "denying"  
 24 Plaintiff's April 2019 claim as alleged in Paragraph 66 of Plaintiff's complaint,  
 25 because the Secretary had paid the claim 3 months earlier in response to the *Olsen I*  
 26 judgment and bad faith ruling. On information and belief, Defendant affirmatively  
 27  
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1 avers that the Medicare Appeals Council was not aware of the *Olsen I* judgment and  
2 bad faith ruling, or the fact that this claim had already been paid at the Secretary's  
3 direction in response to the same, when it issued its decision. On that basis, to the  
4 extent Plaintiff has alleged that Defendant denied this claim in deliberate defiance of  
5 the *Olsen I* judgment and bad faith ruling, Defendant denies the allegation.  
6

7 **B. March 10, 2021 Claim – ALJ Appeal No. 3-10205345873**  
8

9 67. Admitted.

10 68. Admitted.

11 69. Defendant admits that the March 2021 claim was denied initially by  
12 Noridian on April 16, 2021. Defendant admits that the basis for this denial was CMS  
13 Ruling 1682-R and no other, which Plaintiff characterizes as “the ‘bad faith’  
14 grounds.” Defendant affirmatively avers that, as of the date this decision was issued,  
15 the Secretary had not yet advised Noridian of the *Olsen I* judgment or instructed  
16 Noridian to pay Plaintiff's CGM-related claims pursuant to the judgment. On that  
17 basis, to the extent that Plaintiff has alleged that Defendant denied this claim in  
18 deliberate defiance of the *Olsen I* judgment, Defendant denies the allegation.  
19 Defendant concedes, however, that the *Olsen I* judgment should have been more  
20 promptly communicated to Noridian.  
21

22 70. Defendant admits that the March 2021 claim was denied on  
23 redetermination by Noridian on June 16, 2021. Defendant admits that the basis for  
24 this denial was CMS Ruling 1682-R and no other, which Plaintiff characterizes as  
25

“the ‘bad faith’ grounds.” Defendant affirmatively avers that, as of the date Noridian issued its redetermination decision, the Secretary had not yet advised Noridian of the *Olsen I* judgment or instructed Noridian to pay Plaintiff’s CGM-related claims pursuant to the judgment. On that basis, to the extent that Plaintiff has alleged that Defendant deliberately defied the *Olsen I* judgment, Defendant denies the allegation. Defendant concedes, however, that the *Olsen I* judgment should have been more promptly communicated to Noridian. Defendant affirmatively avers that the Secretary directed Noridian to pay this claim in response to the *Olsen I* judgment on July 13, 2021, and that Noridian paid the claim two days later, on July 15, 2021. Below is a timeline of when this claim was paid in relation to the decisions referenced above:

<b>March 10, 2021 Claim</b>	<b>Date</b>
<i>Olsen I</i> Judgment	2/23/2021
Initial Denial by Noridian (MAC)	4/16/2021
<i>Olsen I</i> Bad Faith Ruling	4/20/2021
Redetermination Request (MAC)	5/3/2021
Redetermination Decision (MAC)	6/16/2021
Reconsideration Request (QIC)	6/30/2021
<b>CLAIM PAID</b>	7/15/2021
Reconsideration Decision (QIC)	8/24/2021
ALJ Hearing Request	9/7/2021
ALJ Hearing	10/8/2021
ALJ Decision	10/26/2021
Appeal to Medicare Appeals Council	none
Medicare Appeals Council Decision	none

71. Admitted.

72. Defendant admits that Plaintiff received a decision from Maximus

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1 Federal dated August 24, 2021, denying coverage for the March 2021 claim.  
2 Defendant admits that the basis for this denial was CMS Ruling 1682-R and no other,  
3 which Plaintiff characterizes as “the ‘bad faith’ grounds.” Defendant denies that this  
4 decision had the legal effect of “rejecting” this claim as alleged in Paragraph 72 of  
5 Plaintiff’s complaint, because the Secretary had paid the claim 1 month earlier in  
6 response to the *Olsen I* judgment. On information and belief, Defendant affirmatively  
7 avers that Maximus Federal was not aware of the *Olsen I* judgment, or the fact that  
8 this claim had already been paid at the Secretary’s direction in response to the same,  
9 when it issued its decision. On that basis, to the extent that Plaintiff has alleged that  
10 Defendant deliberately defied the *Olsen I* judgment, Defendant denies the allegation.  
11  
12  
13

14 73. Defendant lacks sufficient knowledge or information to admit or deny the  
15 allegations in this paragraph, and therefore denies the same.  
16

17 74. Admitted that Plaintiff sought expedited access to judicial review.

18 75. Admitted.

19 76. Defendant admits that Plaintiff received an MSN dated October 1, 2021.  
20 Defendant denies that this MSN “indicat[ed] Medicare’s *intention* to pay” some 13  
21 CGM claims; the MSN reflects that Medicare had *already paid* the referenced claims.  
22 Defendant affirmatively avers that the claims referenced in this paragraph were paid  
23 as indicated in the below chart. The remainder of this paragraph consists of Plaintiff’s  
24 characterizations of the MSN, to which no response is required.  
25  
26  
27  
28

CCN	Date of Service	Paid Date	Amount Paid
18137823767001	03/15/2018	07/22/2021	\$1,300.66
18172844803001	06/05/2018	07/15/2021	\$1,300.66
18283843973001	09/27/2018	07/15/2021	\$1,300.66
19008817632001	01/04/2019	07/15/2021	\$1,300.66
19112897095001	04/19/2019	07/15/2021	\$1,430.72
19210873889001	07/08/2019	07/15/2021	\$1,430.72
19296845388001	10/21/2019	07/15/2021	\$1,430.72
20031822855001	01/28/2020	07/15/2021	\$1,430.72
20139845927001	05/15/2020	07/15/2021	\$1,459.92
20230855617001	08/12/2020	07/15/2021	\$1,459.92
20330841967001	11/23/2020	07/15/2021	\$1,459.92
21076836253001	03/10/2021	07/15/2021	\$1,459.92
21204829122001	07/20/2021	08/03/2021	\$1,459.92
21288839976002	10/13/2021	12/27/2021	\$1,459.92

77. Admitted.

78. Defendant admits that 42 C.F.R. § 405.352 governs adjustment of title XVIII incorrect payments, including decreasing any payment to an individual under the Social Security Act to which the individual is entitled. To the extent Plaintiff is alleging that Defendant could invoke § 405.352 to seek recoupment of the payments that Defendant issued for the April 2019 and March 2021 claims, Defendant denies the allegation. The remainder of this paragraph consists of Plaintiff's characterizations and legal conclusions, to which no response is required. The Court is respectfully

SECOND AMENDED ANSWER - 21

1 referred to the cited regulation.

2 **1. October 30, 2021, Decision of ALJ Jason Earnhart**

3 79. Admitted that Plaintiff filed a request for ALJ review on September 7,  
4 2021. Defendant affirmatively avers that the Secretary paid the subject claim  
5 approximately 7 weeks before this request was filed. The remainder of this paragraph  
6 consists of Plaintiff's characterization of his request for ALJ review, to which no  
7 response is required.  
8  
9

10 80. Admitted.

11 81. Defendant admits that ALJ Earnhart issued a decision denying coverage  
12 for the March 2021 claim. Defendant affirmatively avers that this decision did not  
13 have the legal effect of "denying [Plaintiff's] claim" as alleged in Paragraph 81 of  
14 Plaintiff's complaint, because the Secretary had paid the claim approximately 14  
15 weeks earlier in response to the *Olsen I* judgment. To the extent the ALJ's decision  
16 *did* have the effect of "denying [Plaintiff's] claim" as alleged, however, Defendant  
17 admits that the decision was erroneous. On information and belief, Defendant  
18 affirmatively avers that the ALJ was not aware of the *Olsen I* judgment, or the fact  
19 that this claim had already been paid at the Secretary's direction in response to the  
20 same, when he issued his decision. On that basis, to the extent that Plaintiff has  
21 alleged that Defendant deliberately defied the *Olsen I* judgment, Defendant denies the  
22 allegation.  
23  
24  
25  
26

27 82. Admitted.  
28

1 83. Admitted.

2 84. Admitted.

3 85. Defendant admits that the ALJ's decision denied coverage based solely  
4 on CMS 1682-R. Defendant incorporates by reference its answer to Paragraph 81  
5 above.  
6

7 **2. November 2, 2021 Departmental Appeals Board Decision**  
8

9 86. Admitted.

10 87. Admitted that Plaintiff sought review by the Departmental Appeals  
11 Board (DAB). The remainder of this paragraph consists of Plaintiff's characterization  
12 of that request, to which no response is required.  
13

14 88. Admitted that the Departmental Appeals Board issued a decision denying  
15 Plaintiff's request. The remainder of this paragraph consists of Plaintiff's  
16 characterization of that DAB decision, to which no response is required.  
17

18 89. Admitted that the Departmental Appeals Board issued a decision denying  
19 Plaintiff's request. The remainder of this paragraph consists of Plaintiff's  
20 characterization of that DAB decision, to which no response is required.  
21

22 90. Admitted that the Departmental Appeals Board issued a decision denying  
23 Plaintiff's request. The remainder of this paragraph consists of Plaintiff's  
24 characterization of that DAB decision, to which no response is required.  
25

26 **VI. CAUSES OF ACTION**

27 **COUNT I**  
28

1           91. In this paragraph, Plaintiff repeats the paragraphs set forth above.  
2 Defendant incorporates by reference his answers to all of the preceding paragraphs as  
3 if fully set out herein.  
4

5           92. This paragraph consists of a request for relief, to which no response is  
6 required. To the extent that a response is deemed necessary, Defendant admits that he  
7 erroneously denied coverage for the two CGM claims at issue in this case, after  
8 judgment was entered in Plaintiff's favor in *Olsen I*. Defendant affirmatively avers  
9 that both claims were paid on July 15, 2021, as reflected in Paragraphs 64 and 70  
10 above. Defendant consents to administrative remand of this matter with instructions to  
11 have the Secretary vacate the challenged administrative appeal decisions in light of the  
12 Secretary's prior payment of the subject claims. Defendant further affirmatively avers  
13 that on December 28, 2021, through notice-and-comment rulemaking, the Centers for  
14 Medicare & Medicaid Services, U.S. Department of Health and Human Services,  
15 issued a final rule entitled, *Medicare Program; Durable Medical Equipment,*  
16 *Prosthetics, Orthotics, and Supplies (DMEPOS) Policy Issues, and Level II of the*  
17 *Healthcare Common Procedure Coding System (HCPCS); DME Interim Pricing in*  
18 *the CARES Act; Durable Medical Equipment Fee Schedule Adjustments To Resume*  
19 *the Transitional 50/50 Blended Rates To Provide Relief in Rural Areas and Non-*  
20 *Contiguous Areas*, 86 Fed. Reg. 73,860, 73,860–73,911 (Dec. 28, 2021) (the "Final  
21 Rule"). The Final Rule effectively replaces CMS 1682-R, which forms the basis of  
22 Plaintiff's claims in this case, and is effective as of February 28, 2022. The recently  
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28  
SECOND AMENDED ANSWER - 24

1 issued Final Rule makes clear that “claims submitted for CGM sensors and  
2 transmitters used with insulin pumps are being denied inappropriately based on CMS–  
3 1682–R” because that “Ruling only addressed the classification of CGM receivers as  
4 DME and did not address coverage of CGM sensors and transmitters used with insulin  
5 pumps.” 86 Fed. Reg. at 73,898. Further, the Final Rule states that the Secretary “now  
6 believe[s] that ... glucose sensors and transmitters used with insulin pumps ... are  
7 primarily and customarily used to serve a medical purpose.” *Id.* at 73,899.  
8  
9

10 93. This paragraph consists of a request for relief, to which no response is  
11 required. To the extent that a response is deemed necessary, Defendant refers to its  
12 answer in response to Paragraph 92. Defendant admits that he erroneously denied  
13 coverage for Plaintiff’s CGM claims, after judgment was entered in Plaintiff’s favor in  
14 *Olsen I.* Defendant affirmatively avers that both claims were paid on July 15, 2021, as  
15 reflected in Paragraphs 64 and 70 above. Defendant consents to administrative remand  
16 of this matter with instructions to have the Secretary vacate the challenged  
17 administrative appeal decisions in light of the Secretary’s prior payment of the subject  
18 claims, and notes that the Final Rule effective February 28, 2022, resolves the  
19 classification as DME of future CGM claims from Plaintiff and other similarly-  
20 situated CGM claimants.  
21  
22  
23  
24

## 25 COUNT II

26 94. In this paragraph, Plaintiff repeats the paragraphs set forth above.  
27 Defendant incorporates by reference his answers to all of the preceding paragraphs as  
28  
SECOND AMENDED ANSWER - 25

1 if fully set out herein.

2       95. This paragraph consists of a request for relief, to which no response is  
3 required. To the extent that a response is deemed necessary, Defendant refers to its  
4 answer in response to Paragraph 92. Defendant admits that he erroneously denied  
5 coverage for Plaintiff's CGM claims, after judgment was entered in Plaintiff's favor in  
6 *Olsen I*. Defendant affirmatively avers that both claims were paid on July 15, 2021, as  
7 reflected in Paragraphs 64 and 70 above. Defendant consents to administrative remand  
8 of this matter with instructions to have the Secretary vacate the challenged  
9 administrative appeal decisions in light of the Secretary's prior payment of the subject  
10 claims, and notes that the Final Rule effective February 28, 2022, resolves the  
11 classification as DME of future CGM claims from Plaintiff.

12       96. This paragraph consists of a request for relief, to which no response is  
13 required. To the extent that a response is deemed necessary, Defendant refers to its  
14 answer in response to Paragraph 92. Defendant admits that he erroneously denied  
15 coverage for Plaintiff's CGM claims, after judgment was entered in Plaintiff's favor in  
16 *Olsen I*. Defendant affirmatively avers that both claims were paid on July 15, 2021, as  
17 reflected in Paragraphs 64 and 70 above. Defendant consents to administrative remand  
18 of this matter with instructions to have the Secretary vacate the challenged  
19 administrative appeal decisions in light of the Secretary's prior payment of the subject  
20 claims, and notes that the Final Rule effective February 28, 2022, resolves the  
21 classification as DME of future CGM claims from Plaintiff.

**COUNT III**

97. In this paragraph, Plaintiff repeats the paragraphs set forth above. Defendant incorporates by reference his answers to all of the preceding paragraphs as if fully set out herein.

98. This paragraph consists of a request for relief, to which no response is required. To the extent that a response is deemed necessary, Defendant refers to its answer in response to Paragraph 92. Defendant admits that he erroneously denied coverage for Plaintiff's CGM claims, after judgment was entered in Plaintiff's favor in *Olsen I*. Defendant affirmatively avers that both claims were paid on July 15, 2021, as reflected in Paragraphs 64 and 70 above. Defendant consents to administrative remand of this matter with instructions to have the Secretary vacate the challenged administrative appeal decisions in light of the Secretary's prior payment of the subject claims, and notes that the Final Rule effective February 28, 2022, resolves the classification as DME of future CGM claims from Plaintiff.

99. This paragraph consists of a request for relief, to which no response is required. To the extent that a response is deemed necessary, Defendant refers to its answer in response to Paragraph 92. Defendant admits that he erroneously denied coverage for Plaintiff's CGM claims, after judgment was entered in Plaintiff's favor in *Olsen I*. Defendant affirmatively avers that both claims were paid on July 15, 2021, as reflected in Paragraphs 64 and 70 above. Defendant consents to administrative remand

1 of this matter with instructions to have the Secretary vacate the challenged  
2 administrative appeal decisions in light of the Secretary's prior payment of the subject  
3 claims, and notes that the Final Rule effective February 28, 2022, resolves the  
4 classification as DME of future CGM claims from Plaintiff.  
5

#### 6 **COUNT IV**

7 100. In this paragraph, Plaintiff repeats the paragraphs set forth above.  
8 Defendant incorporates by reference his answers to all of the preceding paragraphs as  
9 if fully set out herein.  
10

11 101. This paragraph consists of a request for relief, to which no response is  
12 required. To the extent that a response is deemed necessary, Defendant refers to its  
13 answer in response to Paragraph 92. Defendant admits that he erroneously denied  
14 coverage for Plaintiff's CGM claims, after judgment was entered in Plaintiff's favor in  
15 *Olsen I*. Defendant affirmatively avers that both claims were paid on July 15, 2021, as  
16 reflected in Paragraphs 64 and 70 above. Defendant consents to administrative remand  
17 of this matter with instructions to have the Secretary vacate the challenged  
18 administrative appeal decisions in light of the Secretary's prior payment of the subject  
19 claims, and notes that the Final Rule effective February 28, 2022, resolves the  
20 classification as DME of future CGM claims from Plaintiff.  
21

22 102. This paragraph consists of a request for relief, to which no response is  
23 required. To the extent that a response is deemed necessary, Defendant refers to its  
24 answer in response to Paragraph 92. Defendant admits that he erroneously denied  
25

1 coverage for Plaintiff's CGM claims, after judgment was entered in Plaintiff's favor in  
2 *Olsen I.* Defendant affirmatively avers that both claims were paid on July 15, 2021, as  
3 reflected in Paragraphs 64 and 70 above. Defendant consents to administrative remand  
4 of this matter with instructions to have the Secretary vacate the challenged  
5 administrative appeal decisions in light of the Secretary's prior payment of the subject  
6 claims, and notes that the Final Rule effective February 28, 2022, resolves the  
7 classification as DME of future CGM claims from Plaintiff.  
8  
9

## 10 **COUNT V**

11 103. In this paragraph, Plaintiff repeats the paragraphs set forth above.  
12 Defendant incorporates by reference his answers to all of the preceding paragraphs as  
13 if fully set out herein.  
14

15 104. This paragraph consists of a request for relief, to which no response is  
16 required. To the extent that a response is deemed necessary, Defendant refers to its  
17 answer in response to Paragraph 92. Defendant admits that he erroneously denied  
18 coverage for Plaintiff's CGM claims, after judgment was entered in Plaintiff's favor in  
19 *Olsen I.* Defendant affirmatively avers that both claims were paid on July 15, 2021, as  
20 reflected in Paragraphs 64 and 70 above. Defendant consents to administrative remand  
21 of this matter with instructions to have the Secretary vacate the challenged  
22 administrative appeal decisions in light of the Secretary's prior payment of the subject  
23 claims, and notes that the Final Rule effective February 28, 2022, resolves the  
24 classification as DME of future CGM claims from Plaintiff.  
25  
26  
27  
28

105. This paragraph consists of a request for relief, to which no response is required. To the extent that a response is deemed necessary, Defendant refers to its answer in response to Paragraph 92. Defendant admits that he erroneously denied coverage for Plaintiff's CGM claims, after judgment was entered in Plaintiff's favor in *Olsen I*. Defendant affirmatively avers that both claims were paid on July 15, 2021, as reflected in Paragraphs 64 and 70 above. Defendant consents to administrative remand of this matter with instructions to have the Secretary vacate the challenged administrative appeal decisions in light of the Secretary's prior payment of the subject claims, and notes that the Final Rule effective February 28, 2022, resolves the classification as DME of future CGM claims from Plaintiff.

## COUNT VI

106. In this paragraph, Plaintiff repeats the paragraphs set forth above. Defendant incorporates by reference his answers to all of the preceding paragraphs as if fully set out herein.

107. This paragraph consists of a legal conclusion to which no response is required.

108. This paragraph consists of a legal conclusion to which no response is required.

109. Denied.

110. This paragraph consists of a legal conclusion to which no response is required.

111. Denied.

112. Denied.

## VII. PRAYER FOR RELIEF

The remaining paragraphs of the complaint contain Plaintiff's requested relief, to which no response is required. To the extent that a response is deemed necessary, Defendant admits that he erroneously denied coverage for Plaintiff's CGM claims, after judgment was entered in Plaintiff's favor in *Olsen I*. Defendant affirmatively avers that both claims were paid on July 15, 2021, as reflected in Paragraphs 64 and 70 above. Defendant consents to administrative remand of this matter with instructions to have the Secretary vacate the challenged administrative appeal decisions in light of the Secretary's prior payment of the subject claims, and notes that the Final Rule effective February 28, 2022, resolves the classification as DME of future CGM claims from Plaintiff. Finally, Defendant admits Plaintiff is entitled to costs and reasonable attorneys' fees in an amount to be determined by this Court. With respect to any remaining requests for relief, Defendant denies that Plaintiff is entitled to any other relief.

## AFFIRMATIVE DEFENSES

1. To the extent Plaintiff is seeking an injunction requiring Defendant to grant coverage for CGM claims, the Court lacks jurisdiction to grant such relief.

2. To the extent Plaintiff is seeking appointment of a special master to make coverage decisions on CGM claims, the Court lacks jurisdiction to grant such relief.

1  
2 RESPECTFULLY SUBMITTED: May 11, 2022.

3  
4 Vanessa R. Waldref  
5 United States Attorney

6 s/Brian M. Donovan

7 s/John T. Drake

8 Brian M. Donovan

9 John T. Drake

10 Assistant United States Attorneys  
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**CERTIFICATE OF SERVICE**

I hereby certify that on May 11, 2022, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the following:

Roger M. Townsend: [rtownsend@bjtlegal.com](mailto:rtownsend@bjtlegal.com)

James Pistorino [james@parrishlaw.com](mailto:james@parrishlaw.com)

And to the following non CM/ECF participants: N/A

s/ John T. Drake  
Assistant United States Attorney